

## REMARKS

Claims 1-21 have been canceled. Claims 22-24 are pending.

The specification has been amended (i) to update the priority information and (ii) to include SEQ ID NO:22 as an identifier for the oligonucleotide sequence shown on page 22 at line 25. A substitute Sequence Listing is enclosed with this response to list SEQ ID NO:22. Only the sequence identifier has been included in the specification. Thus, no new matter has been added.

Claims 22-24 have been amended to address the objections set forth on page 3 of the Office Action.

Claims 22-24 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable in view of U.S. Patent No. 6,703,544 and in view of U.S. Patent No. 6,362,399. It is indicated in the Office Action the timely filing of a terminal disclaimer may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting rejection.

It should be noted that the instant application is a divisional application of the application on which the '544 patent issued, which in turn was a divisional application of the application on which US Patent No. 6,362,399 (the parent case) issued.

The instant application and the application on which the '544 patent issued were both divisional applications filed in response to a restriction requirement issued by the U.S. PTO. It is believed that the rejection of claims 22-24 based on the ground of nonstatutory obviousness-type double patenting falls within the prohibition of double patenting rejections under 35 USC 121.

MPEP 804.01 under 35 U.S.C. 121 states:

*"Prohibition of Double Patenting Rejections Under **35 U.S.C. 121** authorizes the \*>Director< to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of **35 U.S.C. 121** prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any*

*divisional application, if the divisional application is filed before the issuance of the patent. The **35 U.S.C. 121** prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.*

The instant application was filed pursuant to a restriction requirement issued by the U.S. PTO and appears to have been filed before the patent(s) issued. Accordingly, withdrawal of the rejection of claims 22-24 on the ground of nonstatutory obviousness-type double patenting is respectfully requested in view of the foregoing.

Claim 24 has been rejected under 35 U.S.C. 101 on the ground that the claimed invention is directed to non-statutory subject matter. Claim 24 has been amended to recite “ food prepared from transgenic soybean seeds..” Support for this amendment can be found throughout the specification and on page 4, line 34. Thus, it is believed that no new matter has been added. Withdrawal of the rejection of claim 24 under 35 USC §101 is respectfully requested.

Claims 22-24 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 22-23 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation of “under conditions that results in expression of the chimeric gene”.

The phrase “ under conditions that results in expression of the chimeric gene” has been replaced with “which express the chimeric gene”. No new matter has been added.

Claim 24 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “sufficient”. Claim 24 has been amended to recite that the nucleic acid sequence has to be sufficient in length to allow for the reduction of the amount of at least one of the soybean seed storage proteins. Support for this clarification can be found in the specification on

page 9 at lines 3-7, page 13 at line 13 through line 10 on page 14. Thus, it is believed that no new matter has been added.

Claims 24 has further been rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation of “reduce” for lacking a comparative basis. Claim 24 has been amended to introduce a comparative basis and recites now that the reduction is in comparison to a non-transgenic soybean. Support for this can be found in Example 1 of the specification. Thus, it is believed that no new matter has been added.

Claims 24 has further been rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “soybean seeds obtained from a soybean plant” for being unclear whether the seed comprises the chimeric gene. This claim has been amended as suggested by the Examiner. Support for this can be found throughout the specification. Thus, it is believed that no new matter has been added.

Claims 24 has further been rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “reducing the amount of at least one soybean seed storage protein in a soybean plant”, for being unclear how seed storage protein that is expressed only in seeds is reduced in the entire plant. This claim has been amended as suggested by the Examiner, namely, the term “plant” has been replaced with the term “seed”. Support for this can be found in the Examples. Thus, it is believed that no new matter has been added.

Withdrawal of the rejection of the claims under 35 USC §112, second paragraph, is respectfully requested in view of the foregoing discussion and amendments.

Claims 22-24 were rejected under 35 U.S.C. 112, first paragraph, as lacking enablement due to the lack of guidance and unpredictability of the related art.

Attention is kindly invited to Example 1 of the instant specification which describes the preparation of a cosuppression construct comprising truncated versions of the  $\alpha$  and  $\alpha'$  subunits of  $\beta$ -conglycinin linked in sense direction to the KTi promoter and terminator. The resulting transgenic embryos showed reduced levels of the  $\alpha$  and  $\alpha'$  subunits of  $\beta$ -conglycinin. Furthermore, one of the embryos Jo1-4 (Table 1, page 19) showed not only

reduced levels of the *Glycine max* microsomal delta-12 desaturase cDNA but also showed reduced levels of the  $\beta$  subunit of  $\beta$ -conglycinin, even though the sequence identity was only 52% with the  $\alpha$  and  $\alpha'$  subunits. This was surprising and unexpected because it was thought that the truncated  $\alpha$  transgene did not possess sufficient similarity to cosuppress the  $\beta$  subunit of the  $\beta$ -conglycinin gene.

Example 2 of the instant specification describes the preparation of a construct containing the *Glycine max* microsomal delta-12 desaturase cDNA (FAD2) linked in an antisense orientation to the  $\beta$ -conglycinin promoter. Transgenic lines showed increased levels of oleic acid, consistent with suppression of FAD2, and a reduction  $\alpha$  and  $\alpha'$  subunits of  $\beta$ -conglycinin. Thus, the promoter region of region  $\beta$ -conglycinin was found to be capable of suppressing expression of the  $\beta$ -conglycinin subunits.

Example 3 of the instant specification describes the preparation of an antisense construct containing the  $\beta$ -conglycinin promoter linked in an antisense orientation to the full length  $\alpha$  cDNAs. The transgenic clones all gave rise to at least one somatic embryo in which the expression of both  $\alpha$  and  $\alpha'$  was suppressed.

Example 4 describes the preparation of cosuppression constructs containing the cDNAs corresponding to the group I cDNA of Glycinin and the group II cDNA of Glycinin linked each in sense direction to the  $\beta$ -conglycinin promoter. The glycinin cDNAs share about 85% sequence identity within the same group and only about 42% to 46% sequence identity between the groups.

In view of the foregoing, It is respectfully submitted that one of ordinary skill in the art that would be able to follow the teachings of the instant invention to reduce expression of the glycinin seed storage protein notwithstanding that “[n]o transgenic soybean embryos or seeds with reduced levels of glycinin using sense or antisense based cosuppression are described.”

No reasonable support was set forth in the Office Action as to why one of ordinary skill in the art that would not be able to follow the teachings of the instant invention to reduce expression of the glycinin seed storage protein other than a lack of an example.

Furthermore, submitted herewith is a copy of Nature, Vol. 404, pages 804-808 (April 20, 2000) which concerns post-transcriptional gene silencing (PTGS). The article states in column 2 on page 804 that PTGS is thought to be an ancient self-defense mechanism evolved to combat infection by viruses and transposons - parasitic stretches of DNA that can hop into an organism's genome, sometimes disrupting important genes.

In plants, the story began with a quest for petunias with a more purple color. It goes on to discuss Jorgensens's work with co-suppression in the third column of page 804 through column 1 on page 805. Jorgensen's thinking was that by increasing or overexpressing the activity of the gene for chalcone synthase the color of the flower could be enhanced. What was discovered is that the "revved-up" chalcone synthase muted both itself and the normal flower gene. Jorgenson's work in co-suppression is more fully discussed in U.S. Patent No. 5,231,020 (issued 1993, copy enclosed).

The '020 patent states in column 8 at lines 1-14 and in column 10 at lines 40-46 that the "homology between the inserted gene and the endogenous gene need not be absolutely identical. Foreign homologous genes would also be subject to this same repression phenomenon. As stated, the repressive effect can occur with many different genes. . . ." Indeed, it is stated in column 7 at lines 39-43 that "the effect may occur where the introduced sequence contains no coding sequence per se, but only intron or untranslated sequences substantially homologous to sequences present in the primary transcript of the endogenous sequence."

Column 8 at lines 1-4 of the '020 patent states further that the "introduced sequence, needing less than absolute homology, also need not be full length, relative to either the primary transcription product of fully processed mRNA. A higher homology in a shorter than full length sequence compensates for a longer less homologous sequence." Thus, even though a full length sequence can be used to cosuppress it is not necessary to achieve the desired effect.

In other words, the desired effect can be achieved **whether or not a full length sequence** is used and **whether or not there is some sequence variation**.

In view of the above, it is believed that one of ordinary skill in the art would be able to following the teachings of the instant invention with respect to using sense or antisense cosuppression based approaches in reducing levels of any soybean seed storage protein. Accordingly, withdrawal of the rejection of claims 22-25 as lacking enablement under 35 U.S.C. §112, first paragraph, is respectfully requested.

It is believed that the rejection of Claims 22-23 under 35 U.S.C.112, written description, is equally inapposite in view of the above-discussion. Accordingly, withdrawal of the rejection of claims 22-25 as lacking written description under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 22-24 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35U.S.C. 103(a) as obvious over Trueblood et al. (US patent NO. 4,267,118, issued on may 12, 1981). The food taught in the reference is a soybean oil, which despite application of different methods, appears to be identical to a food (soybean oil) obtained from the seeds of the invention.

Attention is kindly invited to page 2 at lines 22-24 of the instant specification, where it is stated that:

*New soy based products such as protein concentrates, isolates, and textured protein products are increasingly utilized in countries that do not necessarily accept traditional oriental soy based foods.*

Accordingly, the “food” which constitutes the subject matter of the instant invention is directed to protein concentrates, isolates, and textured protein products, not soybean oil obtained from seeds containing reduced levels of soybean seeds storage proteins. It is also stated on page 1 of the specification at lines 17-20 that soy “protein or protein isolates are already used extensively for food products in different parts of the world. Much effort has been devoted to improving the quantity and quality of storage proteins in soybean seeds.” This is why the instant invention is directed toward altering the seed storage profile of seeds obtained from transgenic soybean plants.

Withdrawal of this ground of rejection is respectfully requested in view of the foregoing discussion.

A petition for a one (1) month extension of time, a Supplemental IDS, a copy of U.S. Patent No. 5,231,020, and a copy of Nature, Vol. 404, pages 804-808 (April 20, 2000) accompany this response.

Please charge any fees or credit any overpayment of fees that are required in connection with the filing of this Preliminary Amendment and Information Disclosure Statement to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company).

Respectfully submitted,

/Lynne M. Christenbury/

LYNNE M. CHRISTENBURY  
ATTORNEY FOR APPLICANTS  
REGISTRATION NO. 30,971  
TELEPHONE: (302) 992-5481  
FACSIMILE: (302) 892-1026

Dated: \_\_\_\_\_